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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/240,455	01/29/1999	DAVID D. MUNDSCHEK	15050.5	7348

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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/27/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/240,455

Applicant(s)

MUNDSCHENK, DAVID D.

Examiner

Todd D Ware

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-5 and 9-69 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### DETAILED ACTION

Receipt of request for extension of time (granted) and request for reconsideration both filed 1-7-02 is acknowledged. Claims 1, 3-5, 9-69 are pending.

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-4, 9-50, 52-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407) in combination with Heiber et al (US 5,766,620; hereafter '620) and further in combination with Dondeti et al (1995) or over Mundshenk et al (WO 97/43407; hereafter '407) in combination with Heiber et al (US 5,766,620; hereafter '620) and further in combination with Siegel et al (1995).

'407 teaches a method of preparing inactivated toxins and bioactive peptides and methods for their administration involving inactivation of a toxin or bioactive peptide with ozone and administering the inactivated peptide parenterally as a vaccination. These peptides may be prepared by the use of ozonated water to prevent the formation of disulfide bridges. The method of '407 also uses the method of preparing a cDNA strand encoding the peptide. For toxins, see the table in column 5. For protein hormones, see

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the paragraph bridging columns 4 and 5. '407 does not teach buccal administration of the peptides or inclusion of a quaternary ammonium salt such as benzalkonium chloride for enhancing mucosal absorption of the peptide in the buccal cavity.

'620 is relied upon for teaching that peptides are buccally administratable.

'620 employs adhesive tablets containing a peptide and a permeation enhancer to deliver the peptides buccally.

Dondeti et al is relied upon for teaching that 0.02% benzalkonium chloride is effective at enhancing mucosal absorption of insulin (pages 102-103).

Siegel et al demonstrates that surfactants such as benzalkonium chloride increase the penetration rate of compounds across oral mucosa.

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407, '620, and Dondeti et al or '407, '620, and Siegel et al to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual that uses benzalkonium chloride to enhance the mucosal absorption of the composition.

3. Claims 5 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mundshenk et al (WO 97/43407; hereafter '407) in combination with Kamiya et al (US 4,948,588; hereafter '588) and further in combination with Dondeti et al (1995) or over Mundshenk et al (WO 97/43407; hereafter '407) in combination with Kamiya et al (US 4,948,588; hereafter '588) and further in combination Siegel et al (1995).

'407 is relied upon for all that it teaches as previously stated. '407 does not teach delivering a composition by spraying to the roof of the mouth or inclusion of a quaternary ammonium salt such as benzalkonium chloride for enhancing mucosal absorption of the peptide in the buccal cavity.

'588 is relied upon for teaching buccal administration of peptides by spraying compositions of peptides with absorption enhancing agents in aerosol and non-aerosol formulations.

Dondeti et al is relied upon for teaching that 0.02% benzalkonium chloride is effective at enhancing mucosal absorption of insulin (pages 102-103).

Accordingly, it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of '407, '588, and Dondeti et al to provide a non-invasive route of administration for inactivated peptides to vaccinate an individual that uses benzalkonium chloride to enhance the mucosal absorption of the composition.

### ***Response to Arguments***

4. As applicant's statements are applicable to both 35 U.S.C. 103(a) rejections, the following response to arguments are based upon both rejections. Applicant's arguments filed 1-7-02 have been fully considered but they are not persuasive. Applicant argues that the peptides of '407 are unlikely to be delivered to the body and that '407 does not teach buccal administration. It is agreed that '407 does not teach buccal administration. '620 is relied upon for teaching buccal administration of peptides. Applicant appears to be arguing against the references individually. One cannot show

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nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant further argues that Dondeti only describes the use of benzalkonium chloride as a preservative. The examiner disagrees. Figure 9 of Dondeti clearly shows that benzalkonium chloride enhances the absorption of insulin. Applicants comments pertaining to these effects being unique to microcrystalline cellulose, however no data supporting such statements have been provided. Accordingly, this argument is not persuasive.

Applicant's statements that the concentrations of Siegel are outside the instant ranges are not understood. Only claims 13-14 require a particular amount of benzalkonium chloride and the amounts taught in Siegel are within these ranges.

### ***Conclusion***


5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
March 21, 2002

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600